

## DEPARTMENT OF COMMERCE

## **Patent and Trademark Office**

COMMISSIONER OF PATENTS AND TRADEMARKS

Washington, D.C. 20231 FIRST NAMED INVENTOR APPLICATION NO. **FILING DATE** ATTORNEY DOCKET NO.

09/422,804

HM12/0606

E

00263/PP/IR

SUITE 700

10/22/99

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SOUTHERN

**EXAMINER** 

MARSCHEL A **ART UNIT** 

PAPER NUMBER

1631 **DATE MAILED:** 

06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

## Office Action Summary

Application No. 09/422,804

Applica...(s

Southern

Examiner

**Ardin Marschel** 

Group Art Unit 1631

| Responsive to communication(s) filed on                                                                                                                                                                                                               |                                                     |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--|
| ☐ This action is <b>FINAL</b> .                                                                                                                                                                                                                       |                                                     |  |
| ☐ Since this application is in condition for allowance except for formal matters, in accordance with the practice under Ex parte Quay@35 C.D. 11; 453 O.G.                                                                                            |                                                     |  |
| A shortened statutory period for response to this action is set to expire longer, from the mailing date of this communication. Failure to respond within tapplication to become abandoned. (35 U.S.C. § 133). Extensions of time may 37 CFR 1.136(a). | the period for response will cause the              |  |
| Disposition of Claim                                                                                                                                                                                                                                  |                                                     |  |
|                                                                                                                                                                                                                                                       | is/are pending in the applicat                      |  |
| Calaim(s) 2-16 have been canceled.                                                                                                                                                                                                                    | is/ar <u>a with the winderstion</u>                 |  |
| Claim(s)                                                                                                                                                                                                                                              | is/are allowed.                                     |  |
| X Claim(s) 1                                                                                                                                                                                                                                          | is/are rejected.                                    |  |
| ☐ Claim(s)                                                                                                                                                                                                                                            | is/are objected to.                                 |  |
| ☐ Claims                                                                                                                                                                                                                                              | are subject to restriction or election requirement. |  |
| Application Papers                                                                                                                                                                                                                                    |                                                     |  |
| ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-                                                                                                                                                                               | 948.                                                |  |
| ☐ The drawing(s) filed on is/are objected to by the                                                                                                                                                                                                   | e Examiner.                                         |  |
| ☐ The proposed drawing correction, filed on is ☐ approved ☐disapproved.                                                                                                                                                                               |                                                     |  |
| ☐ The specification is objected to by the Examiner.                                                                                                                                                                                                   |                                                     |  |
| ☐ The oath or declaration is objected to by the Examiner.                                                                                                                                                                                             |                                                     |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                        |                                                     |  |
| ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C.                                                                                                                                                                             | . § 119(a)-(d).                                     |  |
| ☐ All ☐Some* None of the CERTIFIED copies of the priority doc                                                                                                                                                                                         | uments have been                                    |  |
| received.                                                                                                                                                                                                                                             |                                                     |  |
| ☐ received in Application No. (Series Code/Serial Number)                                                                                                                                                                                             |                                                     |  |
| received in this national stage application from the International Bu                                                                                                                                                                                 | ureau (PCT Rule 17.2(a)).                           |  |
| *Certified copies not received:                                                                                                                                                                                                                       | 0.0440(.)                                           |  |
| ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.                                                                                                                                                                              | C. § 119(e).                                        |  |
| Attachment(s)                                                                                                                                                                                                                                         |                                                     |  |
| ☐ Notice of References Cited, PTO-892                                                                                                                                                                                                                 | .1                                                  |  |
|                                                                                                                                                                                                                                                       |                                                     |  |
| ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948                                                                                                                                                                                             |                                                     |  |
| ☐ Notice of Informal Patent Application, PTO-152                                                                                                                                                                                                      |                                                     |  |
|                                                                                                                                                                                                                                                       |                                                     |  |
| SEE OFFICE ACTION ON THE FOLLOWI                                                                                                                                                                                                                      | NG PAGES                                            |  |

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It is noted that applicant has indicated a desire to submit a preliminary amendment in this application but that a significant amount of time has passed since this 10/22/99 indication.

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because: The Declaration has a defective aspect. The Declaration was copied so close to the top of the page that hole punching to assemble the application file has punched out some of the top wording.

A substitute specification is required because most of the pages as filed are so poorly copied that they are unreadable. The substitute specification filed must be accompanied by a statement that it contains no new matter. Such statement must be a verified statement if made by a person not registered to practice before the Office.

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_ " should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

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A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending application Serial No. 09/422,803. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed

publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. § 102(b) and (e) as being anticipated by Mundy(P/N 4,656,127).

Example 2 of Mundy in columns 10-13, depicted in Figure 8, discloses the preparation of membrane sections with four spots on each section, two spots with pBR322 DNA attached and two spots with pAT153 DNA attached. These spots are available for hybridization as demonstrated by the hybridization of a 20-mer probe that is radioactively labeled with 32P. The plasmid DNA in the spots have a defined sequence either defined by their source or well known well known in the art as for pBR322, for example, or as prepared as discussed in Mundy for pAT153. Mundy also discloses the analysis of the labeled probe via various reactions. Thus, the array of Mundy contains oligonucleotides of different sequence and length. See the plasmid description in column 10, lines 54-60. The above Mundy disclosure reads on the instant claim in that a support has a surface on which is attached oligonucleotides of defined and different sequences in discrete spots or cell location. It is noted that there is no

clear definition of oligonucleotides that defines length limitations that distinguishes the plasmids of Mundy from oligonucleotides cited in the instant claim.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Saiki et al.(Nature 324:163[1986]).

Figure 2 on page 164 of Saiki et al. shows three membrane strips. Consideration of the Figure 2 legend reveals that these 3 strips were prepared identically with nucleic acids spotted as shown with nucleic acids designated as AA thru AC. These spotted nucleic acids are prepared from blood samples of known  $\beta$ -globin genotypes which results in their being of different sequences but defined by said genotypes. Each strip is then hybridized with a different 32P labeled probe which is designated 19C, 19S, and 19A, respectively. As shown in Figure 2 each strip results in the labeled probes hybridizing selectively to the spots thereon thus analyzing the hybridization of said labeled probes. The strips read on the above listed apparatus claim due to the presence of cell locations or spots with different sequence polynucleotides. It is noted that the instant claim cites oligonucleotides as being attached on the arrays but do not define the length of these oligonucleotides such as to prevent the  $\beta$ -globin nucleic acids of Saiki et al. from being reasonably interpreted as oligonucleotides without further claim wording to clearly distinguish the nucleic acids disclosed in Saiki et al.

from the oligonucleotides as instantly claimed. In other words, the instant specification lacks an upper size limit to oligonucleotides attached to arrays.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Brigati et al. (Virology 126:32[1983]).

Brigati et al. disclose the in-situ hybridization of probes onto glass coverslips prepared with immobilized cells infected with various viruses as discussed starting on page 35, first column, in the section entitled "Coverslip and Slide Preparation" through page 39, second column. Figures 4-6 show results that document the hybridizability of labeled probes to certain virally infected cells and not others nor to cellular genomic DNA immobilized also within cells of the array. These constructs read on the instantly claimed apparatus given a lack of a clear definition of the upper size limit of what is meant by the term "oligonucleotide". It is noted that the instant claims cite oligonucleotides as being attached on the arrays but do not define the length of these oligonucleotides such as to prevent the viral nucleic acids of Brigati et al. from being reasonably interpreted as oligonucleotides without further claim wording to clearly distinguish the nucleic acids disclosed in Brigati et al. from the oligonucleotides as instantly claimed. The random degradation of the polynucleotide that is hybridized to the immobilized array and at least partially labeled with 32P is

entitled, "Preparation of hybridization probes".

Several citations have been lined through as not considered on the enclosed PTO Form 1449 due to a lack of a date of publication.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 5, 2000

ARDIN H. MARSCHEL PRIMARY EXAMINER